

**IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK**

ECHO BAY PHARMACEUTICALS, LLC,

Plaintiff,

v.

TORRENT PHARMA, INC.,

Defendant.

Case No.: 1:20-cv-06345

Judge: Barbara C. Moses

SECOND AMENDED COMPLAINT

Plaintiff Echo Bay Pharmaceuticals, LLC (“Echo Bay”) files this First Amended Complaint against Defendant Torrent Pharma, Inc. (“Torrent”), and respectfully alleges as follows:

NATURE OF THIS ACTION

1. This is an action for breach of contract, including express breaches and breaches of implied duties of good faith and fair dealing with respect to such contract, stemming from a business relationship between the parties.

PARTIES

2. Plaintiff Echo Bay is a limited liability company organized under Delaware law, with a principal place of business in Chicago, Illinois.

3. Defendant Torrent is a Delaware corporation, with a principal place of business at 150 Allen Road, Suite 102, Basking Ridge, NJ 07920.

4. Plaintiff Echo Bay is a single member LLC, whose sole member is an individual person domiciled and residing in Chicago, Illinois, and such individual is a citizen of the state of Illinois. Therefore, for purposes of diversity jurisdiction, Plaintiff Echo Bay is a citizen of Illinois.

5. Defendant Torrent is a corporation, formed under the laws of the state of Delaware, and having its principal place of business in New Jersey. Pursuant to 28 USC §§ 1332(c), for purposes of diversity jurisdiction, Torrent is a citizen of both Delaware and New Jersey.

6. Defendant Torrent is not a citizen of Illinois, and Plaintiff Echo Bay is not a citizen of either Delaware or New Jersey. Hence, complete diversity of citizenship exists between Plaintiff and Defendant.

JURISDICTION AND VENUE

7. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1332(a) because complete diversity of citizenship exists between the parties and the matter in controversy, exclusive of interest and costs, exceeds \$75,000.00.

8. This Court has personal jurisdiction over Defendant Torrent in this matter.

9. Among other things, Torrent regularly and systematically ships and sells its products to customers in New York and in this District, and through numerous retail pharmacies located in New York and in this District.

10. Torrent regularly and systematically conducts business within New York and in this District.

11. Moreover, via the choice of jurisdiction and venue provisions in Section 9.6 of the Co-Development Settlement Agreement referenced herein, Torrent has consented to personal jurisdiction and venue in this Court.

12. Venue is proper in this District pursuant to 28 U.S.C. §§ 1391(b)(1). Torrent resides within this district, within the meaning of 28 U.S.C. §§ 1391(c)(2).

BACKGROUND

13. Echo Bay is in the business of developing pharmaceuticals. In 2015, Echo Bay sought to develop a number of generic pharmaceuticals jointly with Bio-Pharm, Inc. (“BPI”), a Pennsylvania corporation also in the business of pharmaceutical development and manufacturing. To do so, Echo Bay and BPI formed an entity called Bio-Pharm, LLC (“BP, LLC”), a Delaware limited liability company. Echo Bay and BPI were the only two members of BP, LLC, each owning one half of the limited liability company.

14. To further the undertaking, BPI and BP, LLC entered into a Supply and Marketing Agreement dated September 23, 2015 (the “SMA”). Pursuant to the terms of the SMA, BPI and BP, LLC were to jointly develop a series of pharmaceutical products, after which BPI and BP, LLC would commercialize those products, including manufacturing, sale and distribution of the same. In 2016 and 2017, BPI and BP, LLC took a number of steps and conducted a number of tasks to develop the products under the SMA.

Torrent’s Acquisition of BPI

15. In late 2017, Torrent became interested in acquiring BPI, including BPI’s manufacturing facility located at 2091 Hartel Street, Levittown, PA 19057 (the “Levittown Facility”).

16. As part of its efforts to acquire BPI, and as conditions precedent to effectuating such acquisition, Torrent required BPI to wind-up its relationship with BP, LLC, including taking steps to (i) terminate the SMA between BPI and BP, LLC, (ii) remove BPI’s ownership interest in BP, LLC, vesting complete ownership of BP, LLC in Echo Bay, and (iii) have BP, LLC change its entity name so that it no longer made reference to “Bio-Pharm.”

17. As a result, in early 2018, Torrent and BPI took steps to formalize Torrent's acquisition of BPI subject to the aforementioned criteria.

18. At or about that time, BP, LLC changed its corporate name from "Bio-Pharm, LLC" to "Innisfree Bio, LLC" ("IB, LLC").

19. At or about that time, BPI and Echo Bay entered into a Membership Interest Transfer Agreement ("MITA"), whereby BPI transferred all units of membership interest in IB, LLC to Echo Bay, such that as a result of such transfer, Echo Bay was the sole owner and member of IB, LLC.

20. Following such transfer, as part of and as a prerequisite to Torrent's acquisition of BPI, BPI, Echo Bay, and IB, LLC entered into a Co-Development Settlement Agreement having an Effective Date of January 18, 2018 (the "CSA"). A true and correct copy of the CSA is attached hereto as Exhibit A.

21. Pursuant to Section 9.16 of the CSA, Echo Bay and IB, LLC were considered one and the same, and any reference in the CSA to Echo Bay included a reference to IB, LLC.

22. In any event, as the sole member of IB, LLC, Echo Bay had no need to continue IB, LLC as a separate corporate entity. IB, LLC was dissolved and voluntarily cancelled on January 22, 2018, four days after the Effective Date of the CSA. At all times relevant hereto, Echo Bay alone performed the duties and obligations of Echo Bay under the CSA.

23. By mutual agreement on December 5, 2018, the parties amended the CSA by executing Amendment No. 1 to the CSA. A true and correct copy of Amendment No. 1 to the CSA is attached hereto as Exhibit B.

24. Upon information and belief, the CSA was authored, prepared and drafted by Torrent and Torrent's counsel, on behalf of BPI, for presentation by BPI to Echo Bay.

25. Pursuant to Section 2.6 of the CSA, the SMA was terminated as of the Effective Date of the CSA.

26. Concurrently with the execution of the CSA, Torrent and BPI entered into a Share Purchase Agreement (“SPA”) pursuant to which Torrent acquired ownership of BPI. As a result, Torrent became the owner of the Levittown Facility, and became the successor in interest to BPI under the CSA.

27. Upon information and belief, the closing of the SPA was completed in January 2018.

28. Upon information and belief, pursuant to Section 9.2 of the CSA, BPI assigned its rights and obligations under the CSA to Torrent.

29. Upon information and belief, on December 21, 2018, Torrent filed with the Pennsylvania Department of State, a Statement of Merger causing BPI to be merged into Torrent. Such merger was accomplished effective January 1, 2019, after which BPI ceased to exist.

30. At all times relevant hereto, following the Effective Date of the CSA, Torrent was obligated to continue BPI’s performance under the CSA, enjoying the benefits inuring to “the Company” (as defined in the CSA) therein, and undertaking the obligations of “the Company” (as defined in the CSA) therein.

31. At all times from January 18, 2018 through the present, Torrent, as assignee of and/or successor in interest to BPI, was obligated to perform under the CSA.

32. Indeed, following the Effective Date, performance under the CSA was undertaken by Torrent, not BPI. For example, (i) Torrent owned the Levittown Facility, (ii) Torrent performed the Development obligations under the CSA, (iii) Torrent filed applications, documents and other

papers with regulatory bodies in its name (not BPI's name), (iv) Torrent corresponded and communicated with Echo Bay directly in its name (not in BPI's name), etc.

33. Pursuant to Section 9.16 of the CSA, because Echo Bay was the sole owner and member of IB, LLC, as of the January 18, 2018 Effective Date of the CSA, and following the dissolution of IB, LLC on January 22, 2018, Echo Bay became the effective contracting party under the CSA, enjoying the benefits inuring to "Echo Bay" (as defined in the CSA) therein, and undertaking the obligations of "Echo Bay" (as defined in the CSA) therein.

34. Thus, commencing with the Effective Date of the CSA, a contractual relationship between Echo Bay and Torrent commenced, governed by the CSA, which continues to the present. The CSA, as amended, is a binding and enforceable contract between the parties.

Echo Bay's Performance and Expectations Under the CSA

35. Beginning on the Effective Date of the CSA, January 18, 2018, Torrent and Echo Bay were obligated to perform their respective obligations under the CSA.

36. At all times relevant hereunder, Echo Bay has fulfilled all of its obligations under the CSA.

37. Specifically, Echo Bay provided Torrent with all artwork, copy or other material developed or produced by IB, LLC or Echo Bay for Product labels, printed packaging materials and Product inserts, as contemplated by Section 4.2 of the CSA.

38. Echo Bay fully performed its obligations with respect to Section 4.3 of the CSA, as Torrent never requested any freedom to operate assessments from Echo Bay.

39. At all times, Echo Bay has been in compliance with the noncompetition obligations of Section 5.1 of the CSA.

40. Echo Bay fully complied with Section 3.5 of the CSA, which was added to the agreement by the December 5, 2018 Amendment No. 1 to the CSA.

41. Having engaged Torrent to Develop and Commercialize the Active Products (as defined herein), Echo Bay had a reasonable expectation that Torrent would take prudent and necessary steps to develop such products in a timely manner so as to enjoy the revenue from the Commercialization of such products.

42. Pursuant to Section 2.2 of the CSA, Torrent received the benefit of a worldwide exclusive right to Commercialize each of the Products, including the Active Products (as defined herein).

Torrent's Obligations and Failures Under the CSA

43. Pursuant to the CSA, Torrent was obligated to complete the remaining Development¹ of the Products listed on Exhibit A of the CSA and undertake Commercialization of the Products.

44. Of the seven (7) Products listed on Exhibit A of the CSA, the parties mutually agreed to forego Development and Commercialization of Product No. 5 - Mupirocin 2% Nasal Ointment and Product No. 6 - Eletriptan Tablets. However, Torrent was to proceed to Commercialization of the other five Products (Product No. 1 - Fluocinolone Acetonide Solution .01%, Product No. 2 - Fluocinonide Solution 5%, Product No. 3 - Pyridostigmine Oral Syrup, Product No. 4 - Felbamate Suspension, and Product No. 7 - Gabapentin Solution) (collectively referred to as the "Active Products").

¹ Capitalized terms used herein correspond to capitalized terms in the CSA shall have the same meaning of those terms as defined in the CSA.

45. To support such efforts, Torrent and Echo Bay were to equally share the Development Expenses for each Product pursuant to the CSA.

46. Torrent commenced, continued and undertook Development efforts of the Active Products at its newly acquired Levittown Facility, where BPI had previously conducted similar efforts.

47. At no time during the Term of the CSA did Torrent either choose to cease contributing Development Expenses with any of the Products, or notify Echo Bay of such an intent, pursuant to Section 8.4(a) of the CSA.

48. In 2019 Torrent undertook and continued a renovation of the Levittown Facility, and claimed that such renovation was part of its continued Development of the Active Products.

49. Upon information and belief, at no time during the Term of the CSA did there occur a period of time of twelve (12) or more successive months in which Torrent undertook no significant Development activities with respect to all of the Active Products. Instead, Torrent has consistently claimed to have continued Development activities with regard to all of the Active Products.

50. Albeit unsuccessfully, Torrent continued its Development work on the Active Products in 2019, and throughout the renovation of the Levittown Facility, including incurring third party charges relating to such Development, and invoicing Echo Bay for the same in accordance with Article III of the CSA. Thus, at no time has there been a period of inactivity as described in Section 8.4(a) of the CSA.

51. Moreover, upon information and belief, Torrent has taken the position that the renovation of the Levittown Facility was due to circumstances outside of Torrent's control. Thus,

to the extent that any delays in Development of the Active Products occurred during such renovation, Section 8.4(a) is inapplicable.

52. Additionally, had there been either an express or deemed cessation of the Development of any Active Products in accordance with Section 8.4(a), Torrent would have been obligated, pursuant to Section 8.4(a)(ii), to perform certain undertakings in favor of Echo Bay, including but not limited to assigning to Echo Bay of (1) all title and interest in any Product Technology and all Intellectual Property for such Pre-ANDA Non-Development Product; (2) the right to complete the Development of such Pre-ANDA Non-Development Product, (3) the right to Commercialize the Pre-ANDA Non-Development Product; and (4) all regulatory filings and approvals related to such Pre-ANDA Non-Development Product and any manufacturing or supply agreement executed by Torrent with respect to such Pre-ANDA Non-Development Product, all within ninety (90) days of such express or deemed cessation of Development.

53. At no time did Torrent undertake any of its obligations under Section 8.4(a)(ii), as described in the preceding paragraph.

54. Thus, Torrent is in breach of the CSA regardless of whether or not Section 8.4(a) was ever triggered. If Section 8.4(a) was never triggered, as Echo Bay contends, then Torrent was obligated to continue Development and Commercialization of the Active Products in a reasonable and prudent manner, which it failed to do. But even if Section 8.4(a) was somehow triggered with respect to any Active Product, then Torrent was obligated to perform the tasks under Section 8.4(a)(ii) with respect to such Active Product, which Torrent failed to do.

55. At no time during the Term of the CSA did Torrent notify Echo Bay of its decision to cease Commercialization of any Product pursuant to Section 8.4(b) of the CSA.

Torrent Botches Pyridostigmine and Other Active Products

56. Product No. 3 - Pyridostigmine Oral Syrup ("Pyridostigmine") had particularly high commercial potential, as it was to be the first generic pharmaceutical of its kind.

57. On or about April 27, 2018, Torrent submitted an abbreviated new drug application (ANDA) for Product No. 3 – Pyridostigmine Bromide Oral Solution USP, 60 mg/5 mL. The U.S. Food and Drug Administration (FDA) assigned this application number ANDA 211936.

58. On or about June 14, 2018, the FDA issued an Acknowledgement ANDA Receipt for the above-referenced application. A true and correct copy of such Acknowledgement ANDA Receipt is attached hereto as Exhibit C. In such Acknowledgement ANDA Receipt, the FDA assigned a GDUFA II goal date for review of February 26, 2019.

59. Similarly, on or about October 12, 2018, Torrent submitted an ANDA for Product No. 7 – Gabapentin Oral Solution, 250 mg/5 mL. The FDA assigned this application number ANDA 212488.

60. On or about November 29, 2018, the FDA issued an Acknowledgement ANDA Receipt for the above-referenced application. A true and correct copy of such Acknowledgement ANDA Receipt is attached hereto as Exhibit D. In such Acknowledgement ANDA Receipt, the FDA assigned a GDUFA goal date for review of August 11, 2019.

61. On or about August 24, 2017, BP, LLC submitted an ANDA for Product No. 1 – Fluocinolone Acetonide Topical Solution USP, 0.01%. The FDA assigned this application number ANDA 210815.

62. On or about October 18, 2017, the FDA issued an Acknowledgement ANDA Receipt for the above-referenced application. A true and correct copy of such Acknowledgement ANDA Receipt is attached hereto as Exhibit E. In such Acknowledgement ANDA Receipt, the FDA assigned a GDUFA II goal date for review of June 23, 2019.

63. On or about June 26, 2017, BPI submitted an ANDA for Product No. 2 – Fluocinonide. The FDA assigned this application number ANDA 210627.

64. On or about August 16, 2017, the FDA issued an Acknowledgement ANDA Receipt for the above-referenced application. A true and correct copy of such Acknowledgement ANDA Receipt is attached hereto as Exhibit F. In such Acknowledgement ANDA Receipt, the FDA assigned a GDUFA II goal date for review of April 25, 2018.

65. Thus, it was the parties expectation that approval for Products 3, 7, 1 and 2 would be forthcoming in February 2019, August 2019, June 23, 2018, and April 25, 2018, respectively. Similarly, for the remaining Active Products, the parties expected approvals in 2018 and 2019. As is customary in the generic pharmaceutical industry, in performing under the CSA the parties were working towards first commercial sale of each of the Active Products on or immediately after final approval on each of the respective GDUFA goal dates identified above.

66. However, rather than receiving an Approval Letter for the Pyridostigmine Product, on February 20, 2019, the FDA issued a Complete Response Letter to Torrent regarding the Pyridostigmine Product , ANDA 211936, in which the FDA refused approval of the ANDA due to deficiencies which the FDA classified as “MAJOR.” These deficiencies included pharmaceutical quality, drug substance, drug product, and facilities inspection deficiencies. In particular, the facilities inspection deficiencies stemmed from a recent inspection of the Levittown Facility in which the FDA field investigator observed objectionable conditions which were conveyed to the facility representative. A true and accurate copy of the February 20, 2019 FDA Complete Response Letter is attached hereto as Exhibit G.

67. Yet Torrent failed to address the objectionable conditions noted by the FDA. From March 11, 2019 through April 9, 2019, the FDA conducted numerous additional inspections of

Torrent's Levittown Facility, and found numerous problems therewith. At least twenty-one (21) days of inspections were conducted, citing eight (8) observations which ultimately led the to the October 28, 2019 Warning Letter described below herein. A true and accurate copy of the FDA Inspection Report is attached hereto as Exhibit H.

68. As documented in Exhibit H, among other issues, the FDA noted that "Equipment used in the manufacture, processing, packing or holding of drug products is not of appropriate design to facilitate operations for its intended use and cleaning and maintenance."

69. The FDA went on to note that Torrent "failed to assure" that its "Water System used for production of OTC and Rx drug products is suitably designed and maintained."

70. The FDA further noted numerous other failures, including (i) a lack of procedures to prevent objectionable microorganisms in drug products, (ii) deficient procedures for cleaning and maintenance of equipment; (iii) insufficient examination and testing of samples to assure that drug products and in-process material conformed to specifications; and (iv) deficient determinations of conformance to appropriate written specifications for acceptance for drug products; among others.

71. In short, under Torrent's management and control the Levittown Facility was simply a mess, and not fit to perform or capable of supporting and/or performing the undertakings and contractual obligations that Torrent had undertaken in the CSA. In fact, the Levittown Facility was not fit to produce any pharmaceuticals for any of Torrent's customers and partners, not just Echo Bay's Active Products.

72. Due to Torrent's complete failure to rectify the issues at its Levittown Facility, the FDA issued to Torrent a Warning Letter, dated October 28, 2019. A true and correct copy of the Warning Letter is attached hereto as Exhibit I. The Warning Letter summarized violations of

current good manufacturing practice (CGMP) regulations for finished pharmaceuticals, specifically citing to 21 CFR, parts 210 and 211. The Warning Letter also found the drugs manufactured at the Levittown Facility to be “adulterated” within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug and Cosmetic Act (“FD&C Act”), 21 U.S.C. 351(a)(2)(B). Thus, the FDA had found Torrent to be violating FDA regulations and U.S. law in operating its Levittown Facility.

73. Indeed, Torrent’s facility mismanagement woes were not confined to its Levittown Facility, and facility issues were pervasive, globally, within Torrent’s corporate culture. In April 2019, the FDA further inspected Torrent’s drug manufacturing facility in Ahmedabad, India, and on October 8, 2019 issued a Warning Letter summarizing “significant violations of current good manufacturing practice[s],” and declaring products manufactured in such facility to be “adulterated” within the meaning of Federal Good, Drug, and Cosmetic Act. A true and correct copy of such FDA Warning Letter is attached hereto as Exhibit J.

**Torrent Ceases Developing Fluocinonide and Withdraws ANDA
Without Notifying Echo Bay or Complying With Section 8.4(a)(ii)**

74. With respect to Product No. 2, Fluocinonide, Torrent received a Major Complete Response Letter from the FDA on July 26, 2020, noting continued issues with the Levittown Facility.

75. On August 6, 2020, Torrent's CEO, Sanjay Gupta, signed and approved an ANDA Withdrawal Request Form to withdraw the ANDA for Fluocinonide. A true and accurate copy of that form is attached as Exhibit M.

76. At Torrent's request, ANDA No. 210627 for Fluocinonide was expressly withdrawn by the FDA.

77. Prior to requesting withdrawal of the ANDA, Torrent had not performed any development activities for Fluocinonide for well over one year. Indeed, Torrent's own documents demonstrate that it had done nothing with respect to development of Fluocinonide, including from the time of the commencement of the CSA.

78. By withdrawing the ANDA for Fluocinonide, Torrent expressly stopped developing Fluocinonide.

79. Additionally, by taking no action to develop Fluocinonide for over twelve months, under Section 8.4 of the CSA, Torrent has been deemed to have ceased development of the same.

80. Among other failures, Torrent failed to have the correct equipment (an XP Suite, or "explosion proof suite") in the Levittown Facility to develop the Fluocinonide product at the time it entered into the CSA and undertook such development obligations - nor did it ever seek to acquire such necessary equipment after the fact. Instead, Torrent just gave up on the Fluocinonide product, and camouflaged its failures by hiding the fact that it did nothing with respect to Fluocinonide and withdrew the ANDA for the same, never communicating to Echo Bay about its actions (or lack of actions).

81. Torrent never informed Echo Bay of Torrent's cessation of development of Fluocinonide, nor its withdrawal of the ANDA for Fluocinonide. Indeed, it is only through documents received in discovery in this case that Echo Bay first learned of Torrent's failure to develop the Fluocinonide product and its withdrawal of the ANDA therefor. Torrent's own internal communications confirm that (i) it was required to keep Echo Bay informed as to development of all of the products, including the Fluocinonide product, with respect to all communications with the FDA, (ii) it did not communicate to Echo Bay that it was dropping development of the Fluocinonide product and filing a withdrawal of the ANDA therefor, and (iii)

it had done nothing to develop or commercialize the Fluocinonide product. A true and accurate copy of said internal communications are collectively attached as Exhibit N.

82. Fluocinonide is a "Pre-ANDA Non-Development Product" within the meaning of Section 8.4(a) of the CDA.

83. At no time did Torrent ever comply with its obligations under Section 8.4(a)(ii) of the CDA, where it was obligated to assign to Echo Bay (the "Pre-ANDA Developing Party" pursuant to Section 8.4 of the CSA) all title and interest in any Product Technology and all Intellectual Property for Fluocinonide; (2) the right to complete the Development of Fluocinonide, (3) the right to Commercialize Fluocinonide; and (4) all regulatory filings and approvals related to Fluocinonide and any manufacturing or supply agreement executed by Torrent with respect to Fluocinonide, all within ninety (90) days of such express or deemed cessation of Development. Indeed, with respect to the aforementioned "regulatory filings and approvals" Torrent did the opposite - instead of assigning them to Echo Bay, they expressly withdrew them, including the Fluocinonide ANDA.

84. By failing to comply with its obligations under Section 8.4(a) with respect to Fluocinonide, and specifically Section 8.4(a)(ii), Torrent has caused significant damages to Echo Bay by depriving it of its ability to continue development of Fluocinonide and the revenues associated with Commercialization of the product, as well as wasting the value of the development efforts and funds that had been invested to date (for which Echo Bay paid).

85. Torrent's withdrawal of the ANDA for Fluocinonide deprived Echo Bay of its contractually granted rights to continue development of the product, and as a result thereof, caused damages to Echo Bay.

Torrent Fails to Communicate With Echo Bay, or Mitigate Damages

86. Following the mounting issues with Torrent's Levittown Facility, Torrent began to understand that it would not be able to produce pharmaceuticals there – either for Echo Bay, or for its other partners/customers.

87. Upon information and belief, Torrent began to contact its other partners/customers to inform them of the issues it was having at its Levittown Facility, and to collaborate with such partners/customers to move projects out of the facility to alternate manufacturing facilities, and undertake other mitigation efforts.

88. Unfortunately, Torrent did not extend the same courtesies to Echo Bay.

89. Rather than communicating with Echo Bay about the Levittown Facility failures, Torrent remained silent, and in fact, tried to cover up and hide these failures. Torrent avoided Echo Bay's multiple inquiries and requests for status updates relating to the Active Products. Furthermore, Torrent never informed or discussed with Echo Bay transferring the Active Products out of the Levittown Facility, and Torrent undertook no efforts to mitigate injury to the Active Products with Echo Bay.

90. Upon information and belief, Torrent ultimately ceased necessary, prudent and reasonable Development and Commercialization efforts on Echo Bay's Active Products in 2019, and never informed Echo Bay of the same.

91. Instead of performing its obligations under the CSA and continuing necessary, prudent and reasonable Development and Commercialization efforts, upon information and belief, Torrent ultimately closed the Levittown Facility, undertaking a significant remodel and overhaul thereof. Upon information and belief, Torrent's Levittown Facility remains closed today. During

the time of its closure, the Levittown Facility was not fully operational, and was incapable of supporting all required Development and/or Commercialization efforts.

92. By failing to perform Development and Commercialization of the Active Products, Torrent destroyed and injured Echo Bay's right to receive the fruits of the parties' agreement, namely the timely development and sale of the Active Products, while at the same time enjoying the exclusive rights licensed to Torrent in Section 2.2 of the CSA.

93. Torrent never informed Echo Bay of the closure and overhauling of the Levittown Facility, nor ever discussed with Echo Bay any measures to complete and/or preserve the Commercialization of the Active Products. Indeed, in closing the Levittown Facility, Torrent unilaterally made the decision to cease all further Development and Commercialization of the Active Products. Instead of correcting the errors raised by the FDA to salvage the Echo Bay Active Products, Torrent simply gave up and closed the Levittown Facility.

Torrent Fails to Pay Development Expenses (or Reimburse Echo Bay for the Same)

94. During the Term of the CSA, Torrent and Echo Bay incurred Development Expenses, including third party expenses, in an effort to develop the Active Products.

95. On at least one occasion, Torrent incurred third-party Development Expenses, and received the benefit of the services from such third party, which it then later refused to pay.

96. For example, in 2018 third-party Nines Consult Pharma LLC ("Nines") performed services relating to the development of Active Products fluocinolone acetonide topical solution, 0.01%, fluocinonide topical solutions, 0.05%, and gabapentin oral solution 250mg/5mL (corresponding to Products 1, 2, and 7 of the Active Products).

97. Such services included formulation development support, review of analytical methods, validation protocols, validation reports, review of batch records, review of stability

protocols and reports, weekly teleconferences, preparation and review of ANDA documents, in relation to Products 1, 2, and 7 of the Active Products (the “Nines Services”).

98. After the Effective Date and during the Term of the CSA, Torrent, both individually and through its acquired entity BPI, directly interacted with Nines, participated in numerous teleconferences and communications directly with Nines, and received the benefit of the Nines Services. Torrent and BPI employees regularly communicated with, corresponded with, and engaged with Nines with respect to the Nines Services, including by way of regular weekly calls scheduled at Torrent/BPI’s request. Examples of such communications between Torrent/BPI and Nines are attached hereto as Exhibit K.

99. Ultimately, Nines issued an invoice in the amount of \$197,300.00, Invoice No. 11919001, dated January 19, 2019 (the “Nines Invoice”), for the Nines Services provided to Torrent. A true and accurate copy of such invoice is attached hereto as Exhibit L. Echo Bay paid for all or some of the Nines Services rendered to Torrent and described in the Nines Invoice.

100. Pursuant to Section 3.1 of the CSA, Torrent and Echo Bay were required to “bear the Development Expenses for each Product in the following proportion: fifty percent (50%) by [Torrent] and fifty percent (50%) by Echo Bay.” Similarly, Schedule 1.6 of the CSA, in Note 1, clearly states that “Spend till Date and Future Estimate are total expenses and ***both BPI [now Torrent] and Echo Bay will bear 50%.***”

101. Notwithstanding that the Nines Invoice was not specifically addressed to Torrent, the Nines Services thereunder were nonetheless procured by Torrent, provided to Torrent, and received by Torrent, all at Torrent’s request, and thus were incurred by Torrent, within the meaning of Section 1.6 of the CSA.

102. Echo Bay sought reimbursement from Torrent for fifty percent of the Nines Invoice, representing Development Expenses incurred by Torrent and related to the Development of Products 1, 2, and 7 of the Active Products.

103. Despite repeated demands from Echo Bay for payment of and/or reimbursement of its share of the Nines Invoice, Torrent has refused to pay for its portion of the Nines Invoice, and Torrent's refusal continues until today.

104. Thus, by failing to pay for its portion of the Nines Invoice, representing services procured by and received by Torrent, and Development Expenses incurred by Torrent, Torrent has breached at least Section 3.1 of the CSA.

Echo Bay's Damages

105. Ultimately, as a result of Torrent's failures at the Levittown Facility, and its failures to cure the defects noted by the FDA, *none of the Active Products ever received FDA approval*, nor were they every fully Developed or Commercialized.

106. Furthermore, Torrent's unilateral action to terminate work on the Active Products caused the Development work and the expenses incurred and paid to be wasted.

107. Specifically, Echo Bay paid to Torrent in excess of \$1,000,000.00 for its share of Development Expenses under Section 3.1 of the CSA. Such investments were squandered as a result of Torrent's abandonment of the Active Products and closing of the Levittown Facility, causing damage to Echo Bay.

108. In accordance with Schedule 1.6 of the CSA, prior to the Effective Date of the CSA, Echo Bay had paid a total of \$723,541.94 in Development Expenses, which were squandered due to Torrent's failures described herein.

109. After the Effective Date of the CSA, upon information and belief, Echo Bay has paid over \$300,000 in additional Development Expenses to Torrent, which were squandered due to Torrent's failures described herein.

110. Pursuant to Section 3.2 of the CSA, Torrent has acknowledged and admitted Echo Bay's successful payment of its share of Pre-Effective Date Development Expenses as indicated on Schedule 1.6, totaling \$723,541.94.

111. Moreover, including the Nines Invoice incurred by Torrent and the Nines Services received by Torrent, Echo Bay expended and incurred approximately \$200,000.00 in Development Expenses for which it sought reimbursement from Torrent, pursuant to Section 3.1 of the CSA. Despite repeated demand for reimbursement by Torrent for Torrent's share of such expenses, Torrent has failed to make any payments on such Development Expenses, which remain due and owing.

112. As a result of Torrent's failure to Commercialize Pyridostigmine, another company, Novitium Pharma, LLC ("Novitium") was first to market with a generic pyridostigmine product. Novitium's product was very successful, generating over \$5 million in revenue in 2019, and even higher sales thus far in 2020. In effect, Novitium was able to enjoy the market exclusivity that should have gone to Torrent/Echo Bay's Pyridostigmine Product, but for Torrent's failures described herein.

113. Had Torrent acted reasonably and in good faith to perform its Development and Commercialization obligations under the CSA, and but for Torrent's breaches described herein, Echo Bay's Pyridostigmine Product would have been the first on the market, would have enjoyed market exclusivity for at least 180 days, would have been the leading generic product of its kind,

and would have been a significant commercial success generating millions of dollars of revenue for Echo Bay under the CSA.

114. The other Active Products also would have enjoyed significant commercial success as well, inuring to Echo Bay's financial benefit as a result of the profit sharing contemplated by Sections 1.7 and 2.4 of the CSA.

115. As a result of Torrent's failure to perform its obligations under the CSA, Echo Bay has suffered damages in excess of \$15 million dollars, exclusive of pre-judgment interest and costs.

FIRST CAUSE OF ACTION

(Breach of CSA)

116. Echo Bay hereby incorporates by reference its allegations contained in the preceding paragraphs of this Complaint.

117. The CSA is a valid and binding contract between Torrent and Echo Bay.

118. On numerous occasions, Torrent breached several express provisions of the CSA, including by:

- (a) performing in contravention of all applicable laws and regulations, including the multiple regulatory failures noted by the FDA as described herein, in violation of Sections 7.1(c) and 9.5 of the CSA, which state in relevant part:

Section 7.1(c): "The executed and delivery of this Agreement and the performance of such Party's obligations hereunder (i) do not conflict with or violate any requirement of applicable laws or regulations of any governmental instrumentality..."

Section 9.5: "Each Party shall comply with all Federal, State and local laws, rules and regulations applicable to its obligations under this Agreement..."

- (b) failing to make payments for Development Expenses incurred by Torrent and failing to reimburse Echo Bay for fifty percent of certain Development Expenses

paid by Echo Bay despite being incurred by Torrent in violation of Section 3.1 and Schedule 1.6 of the CSA, which state in relevant part:

Section 3.1: “The Parties shall bear the Development Expenses for each Product in the following proportion: fifty percent (50%) by Company [Torrent] and fifty percent (50%) by Echo Bay.”

Schedule 1.6: “Spend till Date and Future Estimate are total expenses and both BPI [now Torrent] and Echo Bay will bear 50%.”

- (c) squandering development costs invoiced to and paid by Echo Bay to Torrent under the CSA in violation of Sections 1.6, 3.1 and 3.2 of the CSA;
- (d) failing to perform its Development and Commercialization obligations under Article III of the CSA;
- (e) failing to comply with its obligations under Section 8.4(a) with respect to development of the Fluocinonide product and failing to assign the items required under Section 8.4(a)(ii) to Echo Bay; and
- (f) other breaches that discovery shall expose.

119. The CSA, like all agreements, further includes an implied duty of good faith and fair dealing, and Torrent’s breaches of the implied duty constitute breaches of the CSA.

120. Pursuant to the CSA, Torrent had control, discretion and responsibility for the Development and Commercialization of the Active Products; however, Torrent had no right to simply not perform its obligations.

121. Implied in Torrent’s obligations under the CSA were obligations to act reasonably, diligently and prudently in Development and Commercialization of the Active Products, which Torrent failed to do.

122. On numerous occasions, Torrent breached the implied duty of good faith and fair dealing of the CSA, including by:

- (a) failing to obtain ANDA approvals for the Active Products on or before the respective GDUFA dates for such Active Products;
 - (b) failing to promptly and properly remedy the deficiencies identified by the FDA, including those related to the Levittown Facility;
 - (c) failing to provide appropriate facilities to support Development and Commercialization of the Active Products;
 - (d) failing to communicate with Echo Bay and keep Echo Bay apprised of all the issues related to the Development and Commercialization of the Active Products, including but not limited to, ANDA filings, FDA responses, and the status of the Levittown Facility;
 - (e) failing to advise Echo Bay of Torrent's inability and/or refusal to Develop and Commercialize the Active Products, so that Echo Bay could obtain control of the Products and contract with alternative manufacturers to Commercialize and Develop the Active Products;
 - (f) failing to hire the proper consultants and professionals needed and required to remedy the deficiencies identified by the FDA, including those related to corrections required at the Levittown Facility;
 - (g) unilaterally closing the Levittown Facility and ceasing Development and Commercialization efforts relating to the Active Products, without informing Echo Bay of the same;
 - (h) failing to notify Echo Bay of its cessation of Development of Fluocinonide, and withdrawing the ANDA therefor without notifying or conferring with Echo Bay;
- and

(i) other acts of bad faith that discovery shall reveal.

123. Echo Bay's expectations are reasonable and consistent with the express terms of the CSA because the CSA is silent and/or ambiguous with respect to the performance of Torrent under the CSA.

124. Indeed, in exchange for the exclusive license granted under Section 2.2 of the CSA, it was reasonable for Echo Bay to expect Torrent to diligently develop the Active Products that were the subject of the CSA. Any contention by Torrent that it could simultaneously enjoy such exclusive license but in return would have no performance obligations would be unreasonable in light of the parties' expectations under the CSA.

125. Echo Bay has repeatedly made demand for payment of amounts due under the CSA and stemming from such breaches - but to date, no such payments have been made by Torrent.

126. Echo Bay has been damaged by Torrent's breaches of the CSA.

127. Echo Bay has fully performed all of its obligations under the CSA.

128. Accordingly, Echo Bay seeks and is entitled to a judgment against Torrent that Torrent has breached the CSA, and an award of damages in excess of \$75,000.00 to Echo Bay stemming from such breaches by Torrent.

PRAYER FOR RELIEF

WHEREFORE, Echo Bay Pharmaceuticals, LLC respectfully requests that this Court enter judgment in its favor and against Torrent Pharma, Inc. as follows:

A. Finding that Torrent has breached the CSA, including breaches of both express obligations and implied duties, and awarding Echo Bay all damages stemming from such breaches, including pre- and post-judgment interest and costs;

- B. Ordering Torrent to pay Echo Bay's costs pursuant to 28 U.S.C. § 1920; and,
- C. Ordering such other and future relief as this Court deems just and proper.

Dated: August 23, 2021

Respectfully Submitted,

By: /s/ Vladimir I. Arezina
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